510(K) Summary

JAN 16 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807 92

The assigned 510(k) number is **K082887**

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- **Date Prepared** January 15, 2009

Name of the device:

- **Trade/Proprietary Name** PM-1000F+ Patient Monitor
- **Common Name:** Patient Monitor
- **Classification.**

21 CFR 870 2300	Cardiac monitor (including cardiotachometer and rate alarm)	Class II
21 CFR 870 1025	Arrhythmia detector and alarm	Class II
21 CFR 870 1025	Detector and Alarm, Arrhythmia	Class II
21 CFR 870 1025	Monitor, ST Segment with Alarm	Class II
21 CFR 870 1130	Non-Invasive blood pressure measurement system	Class II
21 CFR 870 1110	Blood pressure computer	Class II

21 CFR 870 2910	Clinical Electronic Thermometers-Temperature Monitor with Probe	Class II
21 CFR 870 2700	Oximeter, Pulse	Class II
21 CFR 870 2710	Ear Oximeter, Pulse	Class II
21 CFR 868 1400	Carbon Dioxide Gas Analyzer	Class II
21 CFR 868 1500	Enflurane gas analyzer	Class II
21 CFR 868 1620	Halothane gas analyzer	Class II
21 CFR 868 1700	Nitrous Oxide gas analyzer	Class II
21 CFR 868 1720	Oxygen gas analyzer	Class II

Legally Marketed Predicate Device.

K043348 PM-8000 Patient Monitor, Shenzhen Mindray Bio-medical Electronics Co , Ltd

K053234 PM-9000 Express Patient Monitor, Shenzhen Mindray Bio-medical Electronics Co , Ltd

K070791 PM Series Patient Monitors, Shenzhen Mindray Bio-medical Electronics Co , Ltd

Device Description.

The PM-1000 F+ Patient Monitor is a battery or line-powered patient monitor The Patient Monitor acquires the physiological signals such as ECG, respiration (RES), non-invasive blood pressure (NIBP), saturation of pulse oxygen (SpO2), temperature (TEMP), invasive pressure (IBP), carbon dioxide (CO2) and anesthetic gases (AG) These physiological signals are converted into digital data and processed The PM 1000F+ Patient Monitor examines the data for alarm conditions and presents them on the color TFT display The Patient Monitor also provides advantageous operating control for the user The optional built-in recorder, the optional CF memory card provides hard copies of all digital data and waveforms as well as tabular and graphic trend information, and storage the previous monitoring data information when power off accidentally

Statement of Intended Use.

The PM-1000F+ Patient Monitor is a vital signs monitor used on human patients The target populations are adult, pediatric and neonatal patients The PM-1000F+ Patient Monitor has many features and functions Its use is through an integrated keypad, knob, and intuitive menu system

The patient parameters that can be monitored by the PM-1000F+ are ECG (3-Lead or 5-Lead selectable), arrhythmia detection, ST segment analysis Heart Rate (HR), Respiration Rate (RESP), Non-invasive Blood Pressure (NIBP), Pulse Oxygen Saturation (SpO2), Temperature (TEMP), Invasive Blood Pressure (IBP), Carbon Dioxide (CO2), and Anaesthetic Gases (AG) Its design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs

The PM-1000F+ Patient Monitor is intended for use in hospital clinical areas such as intensive care units, cardiac care units, operating room, emergency department, to provide additional information to the medical and nursing staff about the physiological condition of the patient The PM-1000F+ Patient Monitor is intended to be used only under regular supervision of clinical personnel and by qualified medical personnel trained in the use of the equipment The intended location of use is clinics The PM-1000F+ Patient Monitor is not intended or recommended for use in a patient's home or residence, or when it has not been ordered by a physician

Comparison of Technological Characteristics:
The PM-1000F+ Patient Monitor is substantially equivalent to systems currently marketed predicate devices The design, components, storage technology and energy source the PM-1000F+ Patient Monitor are similar to the predicate devices The PM-1000F+ provides a means for interfacing with a patient, collecting parameter specific physiological data, and processing the data for alarm generation and display of numeric values and waveforms on a bedside or central monitoring system The parameter's specification of the PM-1000F+ including ECG, RESP, HR, PR, RESP, NIBP, SpO2, CO2, TEMP, IBP, is identical to the predicate devices

Testing
Testing was conducted to validate and verify that the PM-1000F+ Patient Monitor met all design specifications and was substantially equivalent to the predicate devices Testing was performed to demonstrate compliance with the ANSI/AAMI standards EC13-2002, "Cardiac monitors, heart rate meters, and alarms " The PM-1000F+ has also been tested to assure compliance with the requirements of various published standards, including IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-4, IEC60601-2-27, IEC60601-2-30 and ISO14971

Conclusion:
The conclusions drawn form clinical and bench testing of the PM-1000F+ Patient Monitor demonstrates that the device is as safe, as effective, and performs as well to the legally marketed predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JAN 16 2009

Re K082887
PM-1000F+ Patient Monitor
Regulation Number 21 CFR 870 2300
Regulation Name Cardiac monitor (including cardiotachometer and alarm)
Regulatory Class Class II (two)
Product Code DSIMWI
Dated December 22, 2008
Received December 22, 2008

Dear Dr Millan

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050 This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference

to premarket notification" (21CFR Part 807 97) You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Bram D Zuckerman, M D
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K082887

Device Name PM-1000F+ Patient Monitor

Indications For Use

The PM-1000F+ Patient Monitor is a vital signs monitor used on human patients The target populations are adult, pediatric and neonatal patients

The patient parameters that can be monitored with the PM-1000F+ Patient Monitor are ECG(3-lead or 5-lead selectable), Heart rate (HR), Pulse Rate (PR), Respiration rate (RESP), Non-invasive blood pressure (NIBP), Saturation of Pulse Oxygen (SpO2), Temperature (TEMP), Invasive Blood pressure (IBP), Carbon dioxide (CO2) and Anaesthetic gases (AG) Its design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs

This monitor is intended for use in a health care facility setting It is intended for use by qualified medical personnel trained in the use of the equipment

The PM-1000F+ Patient Monitor is not recommended for use in a patient's home or residence, or when it has not been ordered by a physician

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082887